No. 14-1377

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

FERRING, B.V.,

Plaintiff-Appellant

v.

WATSON LABORATORIES, INC. – FLORIDA,

Defendant

APOTEX, INC. AND APOTEX CORP.,

Defendants-Appellees.

On appeal from the United States District Court for the District of Nevada in case nos. 3:11-cv-00481-RCJ-VPC, 3:11-cv-00485-RCJ-VPC, 3:11-cv-00854-RCJ-VPC, and 2:12-cv-01941-RCJ-VPC Judge Robert C. Jones

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RESPONSIVE BRIEF OF DEFENDANTS-APPELLEES APOTEX INC. AND APOTEX CORP

BARRY P. GOLOB
KERRY B. MCTIGUE
DONALD R. MCPHAIL
W. BLAKE COBLENTZ
AARON S. LUKAS
COZEN O'CONNOR
1627 I Street, N.W.
Washington, DC 20006
Tel: (202) 912-4800
Fax: (202) 861-1905
Counsel for Defendants-Appellees Apotex Inc. and Apotex Corp.

CERTIFICATE OF INTEREST

Counsel for Appellees Apotex Inc. and Apotex Corp. certify the following:

1. The full name of every party or amicus represented by me is:

   Apotex Inc. and Apotex Corp.

2. The names of the real parties in interest represented by me is:

   Apotex Inc. and Apotex Corp.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the real parties represented by me are:

   Apotex Holdings Inc., Aposherm Inc., and Apotex Pharmaceutical Holdings Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial or agency or are expected to appear in this court are:

Barry P. Golob
Kerry B. McTigue
Donald R. McPhail
W. Blake Coblentz
Aaron S. Lukas
Cozen O'Connor
1627 I Street, N.W.
Washington, DC 20006

Richard T. Ruzich
Elese Hanson
Cozen O'Connor
333 West Wacker Drive
Suite 1900
Chicago, IL 60606

Ian Scott
Cozen O'Connor
277 Park Avenue
New York, NY 10172

James Bradshaw
Lisa Wiltshire Alstead
McDonald Carano Wilson LLP
100 West Liberty Street, 10th Floor
Reno, NV 89501

Ryan A. Loosvelt
Dominica C. Anderson
Brian A. Neighbarger
Duane Morris, LLP
100 North City Parkway
Suite 1560
Las Vegas, NV 89106

Robert Gould
Duane Morris LLP
190 S. LaSalle Street
Chicago, IL 60603

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I. STATEMENT OF THE ISSUES

In addition to the issues identified by Plaintiff-Appellant Ferring B.V. in its Statement of the Issues, Appellees Apotex Inc. and Apotex Corp. (collectively, "Apotex") identify the following questions presented by this appeal:

1. Whether the district court abused its discretion in entering judgment based on Apotex's supplement to its Abbreviated New Drug Application ("ANDA") that amended the specification defining Apotex's proposed generic product to directly address the issue of infringement.

2. If this Court finds that the district court erred with respect to the first issue, then whether the district court misapplied this Court's decision in *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013) to find that Apotex's ANDA prior to supplement was sufficient evidence for Ferring to meet its burden of proof that Apotex infringed the patents-in-suit under 35 U.S.C. § 271(e)(2).

II. STATEMENT OF THE CASE

Ferring's "Statement of the Case Setting Out the Facts Relevant to the Issues" contained numerous self-serving distortions and irrelevancies. Putting aside Ferring's misrepresentations, Apotex submits the following Statement of the Case:

This is a patent infringement case arising under the Hatch-Waxman Act[1] based on Apotex's filing of ANDA No. 202286 seeking to market a generic version of Ferring's LYSTEDA® (tranexamic acid tablets). Ferring filed complaints against Apotex that alleged infringement of U.S. Patent Nos. 7,947,739 ("the '739 patent," A00019-A00071), 8,022,106 ("the '106 patent," A00072-A00126), and 8,273,795 ("the '795 patent," A00127-A00158) (collectively, "patents-in-suit") on July 8, 2011, November 25, 2011, and November 9, 2012, respectively. The district court subsequently consolidated these cases.

Following the submission of briefing from the parties, the district court held a two-day hearing on August 21-22, 2012 on the construction of various disputed terms from the asserted claims of the patents-in-suit. (A09073-A09325; A09326-A09536.) As a part of that hearing, the district court heard testimony from experts proffered by the parties as to the meaning of certain claim terms to one skilled in the relevant art.

[1] The "Hatch-Waxman Act" is a commonly used term for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

On February 6, 2013, the district court issued a memorandum Order construing the disputed claim terms. (A02491-A02509.) Significantly, at least for purposes of this appeal, the district court construed the term "about" in all disputed instances to mean "approximately" and expressly declined to introduce any specific numerical value or range limitation into this term as the parties had proposed. (A02509.)

A bench trial was held before the Honorable Judge Robert C. Jones in the United States District Court for the District of Nevada between January 21 and January 30, 2014.

During trial, the district court made certain factual findings from the bench. Among those, the district court expressly found that a tranexamic acid product which contained the various ingredients required by the asserted claims of the patents-in-suit but released not less than 74% of the active ingredient within 45 minutes is outside the scope of Ferring's asserted claims. (A08951 at 3-9.) The district court also expressly found that a dissolution specification of not less than 75 percent is outside the scope of Ferring's asserted claims. (A08951 at 10 to A08952 at 7; A08953 at 22 to A08954 at 1.)

Because all of the samples of Apotex's tested tablets released not less than 74% of the active ingredient within that 45 minute time frame, the district court further expressly found that Apotex's tablets did not and would not directly infringe any of the asserted claims under 35 U.S.C. § 271(a). (*See* A08875 at 9-12; A08929 at 12-13.)

Nevertheless, because Apotex's ANDA did not address the amount of active ingredient that would dissolve within 45 minutes, *i.e.*, it did not reveal the particular amount of active ingredient that would dissolve by that time period, the district court expressed concern that Apotex might, at some point in the future, market a product that would meet the dissolution rate limitations required by the claims. (A08945.)

The district court did not, however, enter judgment against Apotex on that basis at the conclusion of the evidence. (A08962; A09017 at 19 to A09019 at 16.) Rather, the district court expressly reserved judgment on whether Apotex's ANDA infringed Ferring's asserted patents for a period of at least two weeks to permit Apotex to add a specification to its ANDA that would dispositively resolve the issue of infringement under 35 U.S.C. § 271(e)(2) in Apotex's favor. (A08951-A08953; A08957-A08962.)

Subsequently, on February 12, 2014, Apotex filed a "Supplement—Changes Being Effected (CBE-0)" at the FDA which added a specification to its ANDA requiring that at least 75% of the active ingredient in Apotex's generic product dissolves within 45 minutes. (A03627-A03637.)

As directed by the district court, Apotex also provided Ferring with a proposed stipulation regarding the supplement to Apotex's ANDA and its effect on Ferring's claims of infringement. (A03624-A03625.) Ferring, however, refused to engage on any potential stipulation, even though it was by then fully aware that Apotex was supplementing its ANDA to add an additional specification that would definitively

address that the amount of active ingredient released from Apotex's tablets at 45 minutes would fall well outside the asserted claims. (A08950-A08954.)

On March 5, 2014, a hearing was held by the district court during which the status and content of Apotex's supplement to its ANDA was discussed. (A09004-A09056.) At that time, the district court instructed Apotex to submit a letter to the FDA providing further detail regarding the district court's findings during trial. (A09025-A09026.) On March 18, 2014, Apotex filed the requisite letter with the FDA. (A05000-A05002.)

On March 19, 2014, the FDA indicated (in writing) that Apotex's supplement to its ANDA had been granted and approved on February 21, 2014. (A05003-A05004.)

In view of Apotex's supplement to its ANDA, on March 24, 2014, the district court entered Judgment for Apotex dismissing Ferring's complaint for patent infringement as moot. (A00018; A05005-A05006.) Ferring immediately appealed to this Court.

III. STATEMENT OF THE FACTS

Ferring's Statement of Facts includes numerous irrelevancies and misrepresentations. Apotex therefore submits the following Statement of Facts that are relevant to the issues on review.

A. Apotex's ANDA

Apotex submitted Abbreviated New Drug Application ("ANDA") No. 202286 to the U.S. Food & Drug Administration ("FDA") on August 31, 2010. (*See* A05049-A05050.) Apotex's ANDA sought FDA approval to market a generic version of Ferring's LYSTEDA® product (tranexamic acid tablets), which is the Reference Listed Drug, or "RLD." (A05053; A05067.)

Apotex attempted to design a generic product that would avoid infringement of Ferring's pending patent applications by dissolving faster than the RLD and yet still be bioequivalent to the RLD. (A08442 at 23 to A08443, A05016; A08461 at 20-25; A04101 at 40:12-21.) In doing so, Apotex relied upon publications, as well as internal testing of tranexamic acid. (A05008-A05014.) Tranexamic acid is a BCS Class III substance, which means that it is highly soluble in water, but exhibits low permeability within the gastrointestinal tract. (*See* A05011; A08414 at 6-10, A08414 at 23 to A08415 at 8; A08416 at 11-14.)

For the RLD, it was known that the T_{max} was around three hours. (A08416 at 20.) So to ensure bioequivalence, Apotex designed its formulation to completely dissolve within an hour, well before T_{max}. (A08416 at 15-22.) Complete dissolution

within an hour is recognized by the FDA as being standard for drug products that are highly soluble and rapidly dissolving, such as Apotex's proposed generic product. (A08461 at 2-25.)

LYSTEDA® was approved by the FDA on November 13, 2009, and shortly thereafter Apotex demonstrated that its generic product was bioequivalent to LYSTEDA®. (A08426 at 7-11; A05125-A05126.)

Apotex's original ANDA also included a specification that required that at least 80% of the active ingredient (tranexamic acid) dissolve within 60 minutes using a USP Type II apparatus under certain conditions. (A05029.) On February 28, 2011, the FDA requested that Apotex conduct additional dissolution tests under slightly different conditions using the USP Type II apparatus. (A05081-A05082.)

Apotex complied with this request and on April 14, 2011, submitted the dissolution data to the FDA. (A05070-A05083.) Subesquently, at the request of the FDA, Apotex amended the dissolution specification in its ANDA to reflect the different dissolution testing conditions requested by the FDA. (A05184-A05253.)

According to FDA guidelines, the dissolution specification in Apotex's original ANDA (*i.e.* the dissolution of at least 80% of the active ingredient within 60 minutes) is for an immediate release product. (A05095.)

Following the presentation of evidence to the district court in January, 2014, Apotex again supplemented its ANDA by filing at the FDA a "Supplement—Changes Being Effected (CBE-0)." (A03627-A03637.) This particular supplement added an

additional dissolution requirement, *viz.*, that not less than 75% of the active tranexamic acid would dissolve within 45 minutes in a USP Type II apparatus under the test conditions requested by the FDA. (A03627-A03628.) The FDA granted Apotex's CBE-0 supplement on February 21, 2014. (A05003.)

Under 21 C.F.R. § 314.70, a filer of an ANDA can supplement its ANDA with an addition to a specification at any time prior to launch of its product. (A05254-A05259; A05162, § VIII.C.2.a.) Such a supplement is considered a "moderate change" by the FDA. (A05161-A05162, § VIII.C.)

Apotex's supplement to its ANDA and the FDA's grant of this supplement occurred prior to the district court's entry of judgment on March 24, 2014, and Apotex's launch of its tranexamic acid product on March 26, 2014.

B. The Patents-In-Suit

The applications that gave rise to the '739, '106, and '795 patents were filed on February 26, 2010, April 30, 2009, and August 13, 2008, respectively. (*See* A00020; A00073; A00128.) Each and every asserted claim of the patents-in-suit requires a tablet formulation that provides "an in-vitro dissolution release rate of the tranexamic acid or pharmaceutically acceptable salt thereof, . . . of less than about 70% by weight . . . at about 45 minutes, ..." (*See* A00068, col. 69, ll. 57-65; A00069, col. 71, l. 22–A00070, col. 72, l. 2; A00121, col. 69, ll. 8-19; A00122, col. 71, ll. 17-28; A00156, col. 35, ll. 37-49.)

C. The District Court's *Markman* Ruling

Following briefing by the parties and a two-day hearing with live testimony from expert witnesses, the district court issued its memorandum Order on February 6, 2013, construing the disputed terms of the asserted claims of the patents-in-suit. (A02491-A02509.)

Among the disputed terms, the district court construed "about" in all challenged contexts to mean "approximately." (A02509.) Of significance to this appeal, the district court declined to limit "about" in the manner proposed by Ferring, *viz.* to impose a specific numerical boundary on the claim term "about" by construing this term to include quantities within ±10% of the specified value. (*See* A02505 at 1 to A02506 at 10; A02506 at 11 to A02507 at 2.)

D. The Trial and Post-Trial Proceedings

At trial, Ferring's expert opined that Apotex's tranexamic acid product infringed the 45 minute dissolution limitations of the patents-in-suit based on his interpretation of "approximately" as covering a range of ±10% with respect to the time values and the percentage of tranexamic acid dissolved.[2] (*See* A07515-A07516.) The district court expressly rejected that testimony, and particularly the expert's

[2] This was the same testimony that Ferring's expert offered at the Markman hearing regarding Ferring's proposed construction for the term "about," which was rejected by the district court in its Order construing the disputed claim terms. (A09124-A09151; A02502-A02507.)

interpretation of "approximately" as encompassing a range of ±10% of the specified value. (A07516-A07520; A08951; A09014 at 21 to A09017 at 4.)

Ferring's expert was then compelled to admit that Apotex had succeeded in designing around the claims of Ferring's patents. (A07732 at 3-7; A08767 at 9-14.) Ferring then admitted that it could not show any of the samples of Apotex's tranexamic acid tablets actually infringed any of the asserted claims of the patents. (A07698; A07741; A08755; A08875.)

Nevertheless, Ferring's expert opined that Apotex's proposed tranexamic acid product would infringe the patents-in-suit because the specified dissolution rate in its ANDA (*viz.* not less than 80% of the active ingredient being dissolved within 60 minutes) left open the possibility that Apotex's tranexamic product might provide a dissolution rate of "less than about 70% . . . released at about 45 minutes." (*See* A07510-A07512; A07708-A07709.) Ferring's expert attempted to bolster this opinion by interpolating an even lower percentage that could be released based on variations in the potency of Apotex's tranexamic acid tablets. (*See* A07504-A07509.)

During its case-in-chief, Apotex proffered both fact and expert witness testimony to show that Ferring's expert was wrong. This included testimony from Ms. Elisabeth Kovacs, Apotex's Chief Scientific Officer of Analytical Operations, who testified that Apotex can measure the amount of tranexamic acid dissolved from its product with a precision of ±0.1% (*see* A08424 at 20 to A08425 at 25; A05108-A05109), and that the tablet-to-tablet variability in the percentage dissolved at various

time points is less than ±3%. (*See* A08426 at 2 to A08427 at 21; A05125-A05126). Apotex's expert, Dr. Mayersohn, testified extensively on how a person of ordinary skill in the art takes a sample using the USP Apparatus Type II Paddle method and opined that his interpretation of "approximately" in the context of the asserted claims of the patents-in-suit would mean a small, fixed period of time such as 10 or 15 seconds. (A08561.) Under that interpretation, Dr. Mayersohn concluded that Apotex's tranexamic acid product could not possibly infringe any asserted claims of the patents-in-suit. (A08565-A08576; A05129-A05130; A05140.)

During the trial, the district court made certain factual findings from the bench, including the finding that a product containing the ingredients recited in the asserted claims, but releasing not less than 74% of the active ingredient within 45 minutes would not meet the "less than about 70% . . . released at about 45 minutes" limitation required by each independent claim of the patents-in-suit. (A08951.) Through these findings, the district court rejected all of Ferring's arguments that relied upon interpolated data. (*See* A07516; A07520; A08951; A09014 at 21 to A09017 at 4.)

Based on the factual findings at trial, Apotex supplemented its ANDA at the FDA to require that its approved product release not less than 75% of the tranexamic acid active ingredients within 45 minutes under the conditions specified in the claims of the patents-in-suit. (A03627-A03637.)

In light of this supplement to Apotex's ANDA and the findings of fact it made from the bench during trial, the district court entered judgment for Apotex dismissing Ferring's complaint for patent infringement as moot. (A00018; A05005-A05006.)

IV. SUMMARY OF ARGUMENT

The district court correctly issued a judgment that Apotex's ANDA did not infringe Ferring's patents. Despite Ferring's statements to the contrary, the district court never entered a judgment of infringement against Apotex, and therefore Ferring is not entitled to any relief under 35 U.S.C. § 271(e)(4). Ferring's purported "finding" of infringement is nothing more than dicta in the background portion of the district court's actual judgment dismissing Ferring's complaint for patent infringement as moot. Having lost at the district court, Ferring is hardly entitled to any relief, much less the removal of Apotex's non-infringing product from the market.

Further, to the extent the district court "found" that Apotex's ANDA prior to supplement infringed Ferring's patents under 35 U.S.C. § 271(e)(2), that finding is clearly erroneous under this Court's precedent. Apotex's ANDA prior to supplement did not address the dissolution rate limitations of the asserted claims, and all of the evidence at trial showed that every tested sample of Apotex's generic product did not meet those limitations. Apotex was therefore entitled to judgment that its ANDA, even without inclusion of an additional dissolution specification, did not infringe Ferring's patents under § 271(e)(2).

Instead, the district court properly considered Apotex's supplement to its ANDA and entered judgment to Apotex and dismissed Ferring's complaint as moot. The judgment was entered in light of the district court's factual findings at trial as to the scope of the asserted claims, which found that a dissolution of not less than 74% at 45 minutes does not infringe the "less than about 70% . . . released at about 45 minutes" limitation required by each independent claim of the patents-in-suit. Based on these findings, prior to entry of judgment by the district court, Apotex supplemented its ANDA to expressly address, and thereby definitively preclude even the argument that its ANDA might permit the marketing of a generic product that met the dissolution rate limitations of the properly construed asserted claims. The district court was well within its discretion to consider this evidence in rendering judgment, and did so when it dismissed Ferring's complaint as moot. Ferring's position that the district court erred in considering Apotex's supplement to its ANDA as a basis for judgment is belied by Ferring's inability to point to a single rule, statute, regulation, or case that prohibits the district court from considering any and all evidence it deems relevant.

V. ARGUMENT

A. Standard of Review

Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). Accordingly, this

Court reviews district court claim constructions *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

This Court reviews evidentiary determinations under the law of the regional circuit. *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1358 (Fed. Cir. 2011). The Ninth Circuit reviews decisions regarding admission of evidence for abuse of discretion. *See, e.g., Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254, 1258 n.5 (9th Cir. 1984) (citing *United States v. Rohrer*, 708 F.2d 429, 432 (9th Cir. 1983)).

Infringement is a question of fact that, after a bench trial, this Court reviews for clear error. *See, e.g., Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) (citing *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). "Under the clear error standard, a reversal is permitted 'only when this Court is left with a "definite and firm conviction" that the district court was in error.'" *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164 (Fed. Cir. 2006) (citing *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004)).

An appellate court must be "especially reluctant" to set aside a finding based on the trial judge's evaluation of conflicting lay or expert oral testimony. *Gibbs v. Pierce Cnty. Law Enforcement Support Agency, Tacoma*, 785 F.2d 1396, 1402 (9th Cir. 1986). The deference due the district court is also given to inferences drawn by the court. *United States v. Schuster*, 734 F.2d 424, 426 (9th Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985).

B. The District Court Correctly Determined That Ferring Is Not Entitled to Relief Under 35 U.S.C. § 271(e)(4)(A)

1. The District Court Never Entered Judgment for Ferring on Its Infringement Claim

Ferring's principal argument on appeal is that the district court erred in failing to grant Ferring the relief provided by 35 U.S.C. § 271(e)(4)(A). This argument, however, is fundamentally and fatally flawed—the district court never entered, and so Ferring did not receive, a judgment of infringement against Apotex under any subsection of 35 U.S.C. § 271, much less § 271(e)(2). Because a judgment is a necessary predicate to the granting of any relief under § 271(e)(4)(A), Ferring's argument must fail. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008) ("Subparagraph (A), however, provides an additional type of relief after a finding of infringement under section 271(e)(2) . . . .") (emphasis added).

Ferring places tremendous reliance on dicta from the district court's Judgment, asserting that "[t]he Court's *single* finding in its abbreviated Judgment was that 'Apotex's approved ANDA No. 202286 infringed . . . .'" (Ferring Br. at 4; A00018.) But this assertion grossly mischaracterizes that quoted statement from the district court's Judgment and its import to this matter.

First, Ferring wrongly suggests that the quoted statement should be construed as a judgment by the district court that Apotex's ANDA prior to supplement infringed Ferring's patents. It was not and should not be so taken—as is plain from the language of the order itself, the district court's Judgment as entered was: (1) the

action was dismissed; and (2) each party was to bear its own costs. That was the only judgment entered by the district court, and anything else cannot form the basis for relief to be granted.[3,4]

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[3] Indeed, if Ferring is correct, then it is entitled to relief even though it lost on the merits and judgment was actually entered against it dismissing its complaint as moot. Such a result would be illogical and manifestly unjust.

[4] Further, Ferring's request for relief under 35 U.S.C. § 271(e)(4) would still be inappropriate even if the district court had "found" that Apotex's ANDA prior to supplement infringed the claims of the patents-in-suit. Section 355(j)(5)(B)(iii) of title 21, United States Code, as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 [hereinafter, "the MMA"], made explicit that § 271(e)(4)(A) relief is not available to a patent holder until after this Court's affirmance of any alleged "finding" of infringement by the district court. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(2006).

> Specifically, the MMA expressly changed § 355(j)(B)(5)(iii)(II) to recite:
> if before the expiration of such [30 month stay] period the district court decides that the patent has been infringed—
>
> (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)A) of title 35[.]

See 21 U.S.C. § 355(j)(5)(B)(iii) (2006) (emphasis added).

The emphasized language was added to the statute and makes it abundantly clear that Congress intended for the patent holder to become eligible for such relief only after the district court's finding of infringement under § 271(e)(2) was affirmed on appeal (or not appealed at all).

The "is affirmed" language that was expressly added by the MMA to 21 U.S.C. § 355(j)(5)(B)(iii) must control Ferring's eligibility for 35 U.S.C. § 271(e)(4)(A) relief because it speaks with specificity to that particular issue and was passed more than twenty years after enactment of § 271(e)(4)(A). *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121, 132-33 (2000) ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.").

Because this Court has not yet affirmed any judgment of the district court that would be Ferring's favor, Ferring's request for relief cannot possibly be ripe (even if Ferring was correct on the issue of infringement by Apotex's ANDA prior to supplement).

Second, the above-quoted statement is hardly the entirety of the district court's Judgment as Ferring suggests. Significantly, Ferring ignores the stipulation of Apotex that was incorporated by reference (although not reproduced for confidentiality reasons) into the district court's Judgment. This stipulation included an identification of the supplement that Apotex had already filed with the FDA adding an express restriction on the dissolution rate of its generic product that indisputably precludes the possibility that Apotex could ever market an infringing generic product. (A05005-A05006.) *See*, *e.g.*, *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000).

Third, to the extent that Ferring contends that relief under § 271(e)(4)(A) is mandatory upon any "finding" of infringement, such would be wholly improper under the Supreme Court's decision in *eBay Inc. v MercExchange L.L.C.*, 547 U.S. 388 (2006). In particular, Ferring seeks to use § 271(e)(4)(A) to compel the district court to order the FDA to re-set the approval date of Apotex's ANDA from January 27, 2014, to the date of patent expiration and thereby preclude Apotex from continuing to market its approved generic product. That is an injunction, pure and simple, and the Supreme Court has held that the Patent Act did not create mandatory injunctions for patent infringement. *See id.* at 394 ("We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such

standards."); *see also SmithKline Beecham Corp. v. Apotex Corp.,* 247 F. Supp. 2d 1011, 1049 (N.D. Ill. 2003) (finding that § 271(e)(4)(A) relief is permissive, and not mandatory, because "'shall versus may' arguments are weak in general and in this case. As the Supreme Court noted in *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 [] (1995), 'Though "shall" generally means "must," legal writers sometimes use, or misuse, "shall" to mean "should," "will," or even "may."'"), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

Ferring cites no authority in its brief for the premise that a district court must enter the relief specified by 35 U.S.C. § 271(e)(4)(A), let alone in the absence of an actual judgment of infringement. Such a judgment was and is lacking here, and so the district court properly concluded that Ferring was not entitled to any relief, whether pursuant to 35 U.S.C. § 271(e)(4)(A) or any other provision.

2. Any "Finding" That Apotex's ANDA Prior to Supplement Infringed Was Clearly Erroneous

To the extent that the district court's choice of words in the dicta preceding its actual judgment could be interpreted as a "finding" of infringement sufficient to trigger the provisions of 35 U.S.C. § 271(e)(4)(A), such a finding was clearly erroneous under this Court's precedent.

More specifically, Apotex's ANDA prior to supplement was silent as to the amount of its proposed generic product that would be dissolved at any of the time points specified in the asserted claims of the patents-in-suit (regardless of the

construction of "about" with respect to amount or time). There is no dispute that Apotex's ANDA dissolution specification was a single point at 60 minutes (*see* A05196; A08433), and that the independent claims of the patents-in-suit do not recite a 60 minute time point. (*See* A07733 at 17-23.) Significantly, the amount of active ingredient dissolved from Apotex's tablets at 60 minutes has no bearing on and is wholly silent as to the issue of infringement because it does not reveal how much active ingredient was dissolved at 45 minutes or at 15 minutes (actual time points recited in the asserted claims).[5]

What is more, Apotex's ANDA specifies that when conducting a single point dissolution test, only the 60 minute time point is tested. (*See* A05204-A05205; A07712 at 22 to A07713 at 8.) Indeed, Ferring's expert on infringement, Dr. Williams, conceded that Apotex's single point dissolution specification provided no information about the percentage of tranexamic acid released from Apotex's product at 15, 45, 90, or 120 minutes, as required by the claims of the patents-in-suit. (*See id.*; A07716 at 22-24; A07742 at 17 to A07743 at 13.) Thus, Apotex's ANDA specification prior to supplement did not define a generic product that met the limitations of the asserted

[5] Insofar as the actual time points recited in the asserted claims are concerned, there is no asserted claim that specifies a percentage dissolution at time points of only 60 minutes and later. Instead, all of the asserted claims specify percent dissolution at time points prior to 60 minutes, and include at least a 45 minute time point. It is undisputed that the minimum amount dissolved at 60 minutes does not reveal the amount dissolved at 45 minutes. (*See* A07712 at 22 to A07713 at 8; A07716 at 22-24; A08571 at 10-17.)

claims. *See Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013).

In circumstances where an ANDA specification fails to directly address the question of infringement because the specification is broad enough to include both a product that infringes and a product that does not infringe, then a district court should consider the ANDA itself, materials submitted to the FDA, and other pertinent evidence provided by the parties. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

Under this Court's precedent, where an ANDA specification does not reveal whether a product will infringe the asserted patents, the proper infringement inquiry requires the fact finder to examine the actual samples and data contained in the ANDA to determine "whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product." *Id.* This Court's holding in *Sunovion* did not narrow this precedent. Indeed, *Sunovion* merely held that an ANDA applicant cannot avoid infringement by making a pledge not to infringe when the ANDA specification is within the scope of a valid patent. *See Sunovion*, 731 F.3d at 1280.

The results from testing of actual samples of Apotex's proposed generic product that were submitted by Apotex to the FDA as part of its ANDA prior to supplement showed that none of those tablets met the dissolution rate limitations of the claims as construed by the district court. And Ferring's expert (Dr. Williams)

confirmed this during his live testimony at trial. (*See* A07698 at 9-17; A07741 at 4-12; A08755 at 13-19.)

Under these facts, to the extent the district court is deemed to have adjudged Apotex's ANDA prior to supplement as infringing the claims of Ferring's patents-in-suit, such a "finding" was clearly erroneous. *See Glaxo*, 110 F.3d at 1571. More specifically, in situations such as this where the approved ANDA specification fails to directly address the question of infringement, then the district court must look at the other evidence to determine "whether [Ferring] has proven by a preponderance of the evidence that [Apotex] will likely market an infringing product." *See id.* at 1570.

Here, that other evidence showed that the product likely to be marketed under Apotex's ANDA would not have met the dissolution rate limitations of the asserted claims. Ferring's expert, for example, admitted that Apotex's proposed generic product released the active ingredient faster than required by the claims of Ferring's patents. (*See* A07698 at 9-17; A07741 at 4-12; A08755 at 13-19.) Indeed, Ferring's expert admitted that Apotex successfully designed around the asserted claims of Ferring's patents. (*See* A07732 at 3-7; A08767 at 9-14.) And Ferring admitted that Apotex's proposed products did not infringe any of the asserted claims. (*See* A08875 at 9-12; A08929 at 12-13.)

Ferring therefore did not prove by preponderance of the evidence that Apotex would likely market an infringing product under its ANDA that specified a dissolution of only not less than 80% in 60 minutes. Indeed, the weight of the evidence,

including the results of testing of actual samples of Apotex's proposed generic product and the testimony of Ferring's own expert, shows precisely the opposite—under its ANDA prior to supplement, Apotex would not have marketed an infringing product. Accordingly, any purported "finding" of infringement by Apotex's ANDA prior to supplement was clearly erroneous.

C. The District Court Did Not Err in Dismissing Ferring's Complaint As Moot Based on Apotex's Supplemented ANDA

1. The District Court's Dismissal Was Not Contrary to Law

In what can only be characterized as an attempt to have one's cake and eat it too, Ferring brazenly criticizes as "lacking in support or explanation," the very same Judgment entered by the district court on which it purports to rely in seeking relief under 35 U.S.C. § 271(e)(4)(A). (*See* Ferring Br. at 37.) Such two-faced tactics should not be countenanced by this Court.

The brazenness of Ferring's criticism of the district court's Judgment is particularly egregious given that it dismissed Ferring's complaint expressly pursuant to, *inter alia*, the fact that Apotex had supplemented its ANDA to expressly address and thereby definitively preclude even the argument that Apotex might market an infringing product. (*See* A05005-A05006.) Moreover, the district court's Judgment unambiguously states (or, in Ferring's parlance, "finds") that "Apotex's action [*i.e.* supplementing its ANDA to include an additional dissolution specification] moots

Plaintiff's Complaint . . . ." (A00018.) Ferring's claim that the district court's Judgment in favor of Apotex is lacking in support is plainly belied by the record.

In fact, contrary to Ferring's arguments, it is Ferring's contention that the district court's Judgment is contrary to the law, including the procedures established by the Hatch-Waxman Act, that is lacking here. Ferring's entire argument in this respect is premised on its plainly erroneous belief that the district court was required to re-set the approval date of Apotex's ANDA, discussed *supra*.

Equally wrong is Ferring's manifest desire to force Apotex into another round of litigation solely to preserve its monopoly even in the face of an indisputably non-infringing generic alternative. If anything is contrary to the procedures established by the Hatch-Waxman Act, it is precisely such pointless litigation.

Finally, Ferring's arguments that the district court's Judgment was inconsistent with the Federal Rules of Civil Procedure, and specifically Rules 59 and 60, ignore a very basic fact—Apotex supplemented its ANDA to preclude even the argument of possible future infringement, and the district court accepted evidence of that fact, before the district court entered judgment in this matter. Since Rules 59 and 60 only apply to matters arising after entry of judgment, they are clearly inapplicable to the district court's consideration of Apotex's supplement to its ANDA prior to entering judgment in favor of Apotex.[6]

[6] Ferring's attempted reliance upon *Allergan, Inc. v. Sandoz Inc.*, Nos. 2:09-cv-97, 2:09-cv-348, 2:09-cv-200, 2:09-cv-344, 2013 WL 6253669 (E.D. Tex. Dec. 3, 2013) is

Nor was the district court's Judgment inconsistent with Rule 52 or Rule 56. As noted above, the district court specifically held that Ferring's complaint was mooted by Apotex's supplement to its ANDA that added a specification that directly addressed this question of infringement. Under this Court's precedent, such a finding was all that was necessary for the district court to enter judgment in favor of Apotex as a matter of law. *See*, *e.g.*, *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241(Fed. Cir. 2000); *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180 (Fed. Cir. 2014).

A district court is within its discretion to consider any evidence prior to entry of judgment. *See United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000) ("[J]udges are entitled to broad discretion when discharging their gatekeeping function."). In bench trials, evidentiary errors are "patently harmless" because "the risk that a verdict will be affected unfairly and substantially by the admission of irrelevant evidence is far less than in a jury trial." *EEOC v. Farmer Bros. Co.*, 31 F.3d 891, 898 (9th Cir. 1994).

"Relevant evidence" is anything "having any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without the evidence." *Id.* at 897 (quoting Fed. R. Evid. 401). Ferring conceded the relevance of Apotex's supplement to its ANDA by relying on a number of similar amendments throughout the trial to support its infringement

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similarly misplaced since Sandoz did not attempt to amend its ANDA specification until after the district court's Judgment was affirmed on appeal.

position. (*See, e.g.,* Ferring Br. at 16-18.) Ferring cannot now duplicitously argue that the district court erred by considering Apotex's pre-judgment supplement to its ANDA in rendering its judgment.

What is more, Ferring cannot argue it was unfairly prejudiced or that the district court was misled by Apotex's supplement to its ANDA because "Rule 403 is inapplicable to bench trials." *See United States v. Preston*, 706 F.3d 1106, 1117 (9th Cir. 2013) (citing *Schultz v. Butcher*, 24 F.3d 626, 632 (4th Cir. 1994), which states that "[f]or a bench trial, we are confident that the district court can hear relevant evidence, weigh its probative value and reject any improper inferences.").

Indeed, Ferring has cited no authority to show that the trial court is not within its discretion to consider any and all evidence through entry of judgment. Ferring's arguments that it did not have an opportunity for discovery or to introduce evidence regarding Apotex's supplement to its ANDA are merely red herrings, as is its argument that "there were significant unresolved factual differences relating to this new alleged evidence." (Ferring Br. at 41.) As mandated by this Court's holding in cases such as, *inter alia*, *Bayer*, once Apotex supplemented its ANDA to directly address the issue of infringement, there were no longer any "genuine issues of material fact" or need for additional evidence. *See Bayer*, 212 F.3d at 1248-49.

2. The District Court Correctly Found that Apotex's Supplemented ANDA Does Not Infringe Any Asserted Claim of the Patents-In-Suit

As described above, during the course of proceedings in this matter (and some six weeks before the entry of judgment), Apotex supplemented its ANDA to expressly speak to the issue of whether its generic product could meet the dissolution rate limitations of Ferring's asserted claims. (*See* A03627-A03637; A08951 at 18 to A08952 at 9.) The specification in Apotex's supplemented ANDA therefore defined its generic product in a way that directly addressed and disposed of the question of infringement. *See Bayer*, 212 F.3d at 1249. Apotex was therefore entitled to a judgment of non-infringement as a matter of law. *See id.*

More specifically, in *Bayer*, the patent claim at issue required a specific surface area of the particles of active ingredient to lie within a particular numerical range. *See id.* at 1246. Although the originally-filed ANDA did not include any particular limits for the surface area of the particles of active ingredient, during litigation against the patent holder, the ANDA filer supplemented its ANDA to specify that is product would only contain particles that had a surface area greater than the maximum value of the claimed range. *See id.*

Based on that supplement, much as here, the district court in *Bayer* found that the generic product to be marketed would not infringe the patent-in-suit. *See id.* at 1247. The district court therefore granted summary judgment of non-infringement to the ANDA filer, based on the undisputed fact that the supplemented ANDA

specified that the product to be marketed would only contain particles of active ingredient that were outside the claimed range. *See id.* at 1247, 1251.

This Court subsequently affirmed the district court in *Bayer*, noting that the only drug that an ANDA filer can legally market is defined by the specification(s) contained within the ANDA that is approved by the FDA. *See id.* at 1250. Because an ANDA filer is required by law to only market product(s) that comply with the specification(s) in an approved ANDA, and faces civil and criminal penalties for failure to do so, this Court held that the patent holder could not show, as a matter of law, that the approved generic product would infringe its claims. *See id.* at 1249-50; *see also Alcon Research, Ltd. v. Barr Labs., Inc.*, Case No. 745 F.3d 1180 (Fed. Cir. 2014); *In re Brimonidine Patent Litig.*, 643 F.3d 1366 (Fed. Cir. 2011); *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.").

Much as in each of those cases, Apotex's supplemented ANDA includes a specification that directly addresses the issue of infringement, *viz.* the requirement that not less than 75% of the active ingredient in the product dissolve within 45 minutes. (A03627-A03637.) The district court found that this dissolution specification does not infringe any of the asserted claims because each requires less than about 70% of

the active ingredient dissolve within that same time frame. (A08951 at 3-9.) What is more, the district court made this finding after extensive testimony from Ferring's expert, Dr. Robert O. Williams, and from Apotex fact and expert witnesses.

Ferring now seeks to cast doubt on whether Apotex can comply with its ANDA specification. However, focusing on what Apotex will market under its ANDA, under the current ANDA specification, Apotex is either marketing a drug with a dissolution of not less than 75% in 45 minutes, which the district court deemed to be non-infringing, or Apotex is not, legally, marketing any drug under its ANDA. *See, e.g., Bayer*, 212 F.3d at 1250. This fact simply is not subject to dispute, as this Court has repeatedly held in similar cases. *See id.* Accordingly, contrary to Ferring's assertions, the undisputed evidence in this case actually establishes that Apotex will never market a product that infringes Ferring's asserted claims. The district court's dismissal of Ferring's complaint was therefore correct.

Finally, to the extent Ferring tries to raise issue with the district court's construction of the term "about" as used in the asserted claims, Ferring cannot escape the fact that the district court just simply did not believe the testimony of Ferring's expert

More specifically, this Court has repeatedly held that disputed claim terms are to be construed first with reference to the intrinsic evidence, including the language of the claims, the specification and the prosecution history of the patent at issue. *See*, *e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc). A court

may also consider extrinsic evidence, such as the testimony of witnesses regarding the ordinary meaning of the term to one skilled in the art, but extrinsic evidence is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *See id.* at 1319.

In this case, the district court considered the intrinsic evidence and determined that the patentee had not attempted to define this term numerically, much less to the degree proposed by Ferring (*viz.* ±10% of the specified value). *See* A02502 at 12-13. Such a determination was fully consistent with this Court's precedent. *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter.").

The district court also held a hearing at which it heard testimony from expert witnesses regarding the ordinary meaning of the term "about" to one skilled in the relevant art. Included in that testimony was the testimony of Ferring's expert, Dr. Williams, who testified that, in his opinion, one skilled in the art would construe the term "about" in the asserted claims to mean ±10% of the specified value. (*See* A09124-A09151.)

Based on the totality of the evidence, however, the district court expressly rejected Ferring's contention that "about" should include quantities within ±10% of the specified value (and, at least implicitly, also rejected the testimony of Ferring's expert in support thereof). (*See* A02505 at 1-3; A02506 at 11-12.) Rather than import any specific numerical range into the asserted claims, the district court construed the

term "about" to mean "approximately" based on its ordinary meaning to one skilled in the art. (*See* A02509.) Ferring cannot show any error in this construction, and the testimony of its expert is insufficient in and of itself to overcome the district court's sound reasoning. *See Phillips*, 415 F.3d at 1318. ("[E]xtrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.").

Ferring alleges that "Apotex declined to present at trial any testimony or other evidence disputing Ferring's interpretation of the term 'about' when used in connection with the release rates in the asserted patent claims." (Ferring Br. at 44.) This allegation, however, is simply false and seeks to distort the reality of what actually happened at trial—Apotex did not need to present any affirmative evidence or testimony to rebut Ferring's interpretation of the term "about" in the context of the time values recited in the asserted claims <u>because the district court had already expressly rejected that interpretation during Ferring's case-in-chief</u>. (*See* A07515 at 10 to A07520 at 18.) Nonetheless, Apotex presented testimony from Dr. Michael Mayersohn who testified extensively on how a person of ordinary skill in the art takes a sample using the USP Apparatus Type II Paddle method and opined that his interpretation of "approximately" in the context of the asserted claims of the patents-in-suit would mean, at least with respect to time, a small, fixed value such as 10 or 15 seconds. (A08561-A08576.)

Even worse is Ferring's allegation that it "presented undisputed evidence at trial that 'about 70%' in the patent claims encompasses values up to 77% . . . ." (Ferring Br. at 42.) Such is simply not true. Apotex presented testimony from Ms. Elisabeth Kovacs, Apotex's Chief Scientific Officer of Analytical Operations, who testified that Apotex can measure the amount of tranexamic acid dissolved from its product with a precision of ±0.1% (*see* A08424 at 20 to A08425 at 25; A05108-A05109), and that the tablet-to-tablet variability in the percentage dissolved at various time points is less than ±3%. (*See* A08426 at 2 to A08427 at 21; A05125-A05126). In finding that Apotex's ANDA specification of not less than 75% dissolved in 45 minutes does not infringe Ferring's asserted claims, the district court expressly rejected Dr. Williams' testimony that "about 70%" in the context of the patent claims would encompass values as high as 77%.[7] (A08951 at 3-9; A09014 at 21 to A09017 at 4.)

Moreover, as discussed above, not only was Ferring's evidence disputed at trial by both Apotex's expert and its fact witness, but the district court itself also expressly disagreed with the testimony of Ferring's expert on this issue while he was still on the stand.

[7] Under Ninth Circuit law, an appellate court must be "especially reluctant" to set aside a finding based on the trial judge's evaluation of conflicting oral testimony. *See, e.g.*, *Gibbs v. Pierce Cnty. Law Enforcement Support Agency, Tacoma*, 785 F.2d 1396, 1402 (9th Cir. 1986).

The district court therefore correctly found that Apotex's supplemented ANDA did not infringe Ferring's asserted claims because it expressly defined Apotex's generic product to preclude the possibility that Apotex might market a product that infringed the properly construed claims.

VI. CONCLUSION

The district court properly did not grant Ferring its desired relief under 35 U.S.C. § 271(e)(4)(A) because Ferring could not and still cannot show that either of the necessary prerequisites has been met, *i.e.* the district court never entered judgment that Apotex's ANDA prior to supplement infringed any claim of the patents-in-suit as required by 35 U.S.C. § 271(e)(4)(A) nor did this Court affirm any judgment of infringement (to the extent one even ever existed) as required by 21 U.S.C. § 355(j)(5)(B)(iii). Further, the relief desired by Ferring is in no way required by statute, but instead rests within the equitable discretion of the district court.

Moreover, had the district court actually adjudged Apotex's ANDA prior to supplement as infringing, such would have been clear error. It is undisputed that Apotex's ANDA prior to supplement did not address whether the dissolution rate limitations of the asserted claims would be met by Apotex's proposed products. Nor is it disputed that every tested sample of Apotex's proposed generic product failed to meet those dissolution rate limitations. Therefore, Apotex was, and is, therefore entitled to a judgment that Ferring failed to meet its burden of proof that Apotex's ANDA infringed any asserted claim of Ferring's patents.

The district court did correctly determine that Apotex's supplemented ANDA did not infringe any claim of Ferring's patents because Apotex's ANDA now addresses the dissolution rate limitations of the asserted claims. Indeed, the specification in Apotex's supplemented ANDA defines its generic product in a way that directly addressed and disposed of the question of infringement. Therefore, Apotex was, and remains, entitled to judgment as a matter of law that the filing of Apotex's supplemented ANDA was not an act of infringement under 35 U.S.C. § 271(e) and that the FDA-approved sale of a product pursuant to Apotex's supplemented ANDA would not be an act of infringement under 35 U.S.C. § 271(a).

The district court's Judgment should be affirmed.

CERTIFICATE OF SERVICE

The foregoing non-confidential Responsive Brief of Defendants-Appellees Apotex Inc. and Apotex Corp. was electronically filed with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on May 7, 2014. All participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: May 7, 2014

Respectfully submitted,

/s/ Barry P. Golob
BARRY P. GOLOB
KERRY B. MCTIGUE
DONALD R. MCPHAIL
W. BLAKE COBLENTZ
AARON S. LUKAS
COZEN O'CONNOR

Counsel for Defendants-Appellees Apotex Inc. and Apotex Corp.

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing RESPONSIVE BRIEF OF DEFENDANTS-APPELLEES APOTEX INC. AND APOTEX CORP. contains 8,972 words as measured by the word processing software used to prepare this brief.

Dated: May 7, 2014

Respectfully submitted,

/s/ Barry P. Golob
BARRY P. GOLOB
KERRY B. MCTIGUE
DONALD R. MCPHAIL
W. BLAKE COBLENTZ
AARON S. LUKAS
COZEN O'CONNOR

Counsel for Defendant-Appellees Apotex Inc. and Apotex Corp.